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EXAMINER	
WESTERBERG, NISSA M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,984	MULYE, NIRMAL	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 62* is/are pending in the application.

4a) Of the above claim(s) *1 – 37, 39, 49 – 53, 57, 58, 61 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38, 40 – 48, 54 – 56, 59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group III, and species of microcrystalline cellulose as the cellulose species, a sustained release carrier of hydroxypropylmethylcellulose in combination with xanthan gum and metformin as the drug in the reply filed on December 13, 2007 is acknowledged. The traversal is on the ground(s) that groups II and I should be considered one invention because the subject matter of group I is generic to the subject matter of group II; that group III is directed to the product of group I/II and group IV is directed towards the use of the products of groups III and therefore the groups are related and not independent and that the class and subclass of the groups are the same. For the species election, it was not shown that the species are independent and distinct.

This is not found persuasive because the restriction between groups I and II is subject to the nonallowance of the linking claim 37. The Examiner has acknowledged potential overlap betweens group I and II using linking claim practice and should claim 37 be found allowable, the restriction requirement between these two groups would be withdrawn. As shown on p 6 of the requirement for Restriction/Election different class and subclass is only one of five criteria that establish a serious search and examination burden. Applicant has not addressed how or why the assertions of distinctness between the four groups put forth by the Examiner are not sufficient.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1 – 62 are pending. Claims 1 – 37, 39, 49 – 53, 57, 58, 61 and 62 are withdrawn as not being drawn to the elected invention. Claims 38, 40 – 48, 54 – 56, 59 and 60 are currently under examination.

Drawings

2. The drawings are objected to because the dark gray background color of the graph in Figure 2 mostly obscures the data points and lines on the graphs. The lack of contrast between the background and that data makes the information presented on the graph difficult to discern. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The use of the trademark "Aerosil" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 38, 40 – 48, 54 – 56, 59 and 60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 17, 25 – 30, and 45 of U.S. Patent No. 6,416,786 in view of Tyebji et al. (WO 03/026637). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass sustained release pharmaceutical carriers solid dosages. The claims of the instant application require a

drug, a sustained release carrier, a lubricant, a water insoluble or partially water soluble cellulose and maltodextrin. The solid pharmaceutical tablet of '786 comprise a pharmaceutical active ingredient (drug), a sustained release carrier which comprises a synergistic combination of a hydrocolloid such as xanthan gum and a cellulose ether such as hydroxypropylmethyl cellulose. Additional ingredients explicitly claimed include excipients (claim 10) and lubricants (claim 17). As disclosed in Tyebji et al., excipients are routinely added to pharmaceutical formulations include microcrystalline cellulose (a water insoluble or partially insoluble cellulose compound) and dextrins (p 14, ln 14 – 19) such as maltodextrin. The examples of tablets in Tyebji et al. (p 20 onward) include multiple ingredients with the same function (e.g. multiple ingredients that act to improve the compressibility of the core). It would be obvious to one of ordinary skill in the art to include the excipients that are optional in the claims of '786 to arrive at the claims of the instant application. Given the functional equivalence taught by Tyebji et al. of these ingredients, one of ordinary skill in the art would have also had a reasonable expectation of success at the time when substituting functional equivalents.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 38, 40 – 48, 54 – 56, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyebji et al. (WO 03/026637).

Tyebji et al. discloses a dosage form for the treatment of diabetes mellitus that comprises a controlled release formulation of a biguanide drug such as metformin (p 1, ln 3 – 5). In example 3 (p 23, ln 10 – p 24, ln 13), a controlled release tablet of metformin is prepared. Stage A of the tablet comprises the active ingredient metformin, two different types of HPMC (hydroxypropylmethylcellulose), microcrystalline cellulose and xanthan gum. The combination of HPMC as the cellulose ether, a hydrophilic polymer, and xanthan gum results in a swellable polymer (p 13, ln 20 – p 14, ln 2). The swellable polymers result in the controlled or sustained release of the active ingredient. Microcrystalline cellulose, a water insoluble or partially water insoluble cellulose, is present in the tablet in an amount of 4.76% w/w. Microcrystalline cellulose is taught as an excipient that improves the compressibility of the core composition (p 14, ln 14 – 15). Silicified microcrystalline cellulose is also taught as a functional equivalent (p 14, ln 15). In stage C, colloidal silicon dioxide is present in an amount of 0.95% w/w. The colloidal

silicon dioxide also functions to improve the compressibility of the composition (p 14, ln 13 – 16). Additional functional equivalents of colloidal silicon dioxide include dextrins (p 14, ln 15). Maltodextrin is a dextrin that is a functional equivalent to the other ingredients, as evidenced by col 6, ln 1 – 14 of US Patent 6,372,255. Also present in stage C of example 3 is magnesium stearate, a lubricant (p 18, ln 3 – 4 of the instant application).

In the above mentioned composition (example 3), the ratio of the microcrystalline cellulose to colloidal silicon dioxide is approximately 5:1. The amount of colloidal silicon dioxide and cellulose ether compounds (HPMC K4M, HPMC K100M and Methocel® E5) present in this composition totals 21.166% w/w. The ratio of the cellulose ether compounds to xanthan gum is approximately 4:1. The disclosure states that when a combination of HPMC and xanthan gum is used, the HPMC may be present in a concentration ranging from about 10 – 20 % w/w while the amounts of xanthan gum that can be used in the preferred embodiments may vary from about 5 to about 20 % w/w. With those ranges of ingredients, the ratio of cellulose ether to xanthan gum can range between 4:1 and 1:2.

The examples in Tyebji et al. do not exemplify maltodextrin as an ingredient in such compositions. However, dextrins are taught as functionally equivalent to other ingredients that are present in the exemplified composition. The discovery of an unappreciated property, such as the ability of an ingredient commonly added as an excipient to alter the release rate of the active ingredient, is not a patentable discovery (see MPEP 2112). One of ordinary skill in the art would have a reasonable expectation

of success when replacing one functional equivalent (colloidal silicon dioxide) with another (maltodextrin). If used in the same amounts, the total weight and weight ratios of the various ingredients meets the limitations set forth in the claims of the instant application.

Therefore the claims of the instant application would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Claims 38, 40 – 48, 54 – 56, 59 and 60 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER